

## INSTRUCTIONS FOR PREPARATION OF FORM RHS 8-5I

### INSTRUCTIONS:

1. Read the regulations below governing the use of radioactive material under the General License.
2. Please print or type the name and address of the physician, clinical laboratory, hospital, or veterinarian for whom or for which Form 8-5I is filed. (Item 1)
3. Please print or type the address of the place of use if different from Item 1. (Item 2)
4. Please indicate users status. (Item 3)
5. Complete certification. (Item 4)
6. Submit Form 8-5I in duplicate to:

Division of Radiological Health  
3rd Floor, L&C Annex  
401 Church Street  
Nashville, TN 37243-1532  
Attention: Licensing Section

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### Excerpt From "State Regulations for Protection Against Radiation"

- (a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of (b), (c), (d), (e) and (f) of this paragraph (7), the following radioactive materials in prepackaged units for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:
1. Iodine-125, in units not exceeding 10 microcuries each.
  2. Iodine-131, in units not exceeding 10 microcuries each.
  3. Carbon-14, in units not exceeding 10 microcuries each.
  4. Hydrogen-3 (tritium), in units not exceeding 50 microcuries each.
  5. Iron-59, in units not exceeding 20 microcuries each.
  6. Cobalt-57, in units not exceeding 10 microcuries each.
  7. Selenium-75, in units not exceeding 10 microcuries each.
  8. Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

- (b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by (a) of this paragraph (7) until he has filed an application for and received from the Department a copy of Form RHS 8-5I with number assigned. The general licensee shall furnish on the application the following information and such other information as may be required by that form:

1. Name and address of the licensee;
2. The location of use; and
3. A statement that the licensee has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive materials as authorized under this general license and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.

- (c) A person who receives, acquires, possesses or uses radioactive material pursuant to this general license shall comply with the following:

1. The general licensee shall not possess at any one time, pursuant to this general license, at any one location of storage or use, a total amount of iodine-125, iodine-131, cobalt-57, selenium-75 and/or iron-59 in excess of 200 microcuries.
2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
3. The general licensee shall use the radioactive material only for the uses authorized by (a) of this paragraph (7).
4. The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it by a license pursuant to this Chapter 1200-2-10, from the U.S. Nuclear Regulatory Commission, or an Agreement State or Licensing State nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
5. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in (a) of this paragraph (7) as required by 1200-2-5-17.

- (d) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to (a) of this paragraph (7):

1. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, cobalt-57, iron-59, or Mock Iodine-125 to persons generally licensed; and
2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

- (i) This radioactive material may be received, acquired, possessed and used only

by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

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(name of manufacturer)

- (ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

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(name of manufacturer)

- (e) The licensee possessing or using radioactive materials under this general license shall report in writing to the Director, Division of Radiological Health, 150 Ninth Avenue North, Nashville, Tennessee 37203, any changes in the information furnished by him in the application submitted pursuant to subparagraph (b). The report shall be furnished within 30 days after the effective date of such change.
- (f) Any person using radioactive material pursuant to this general license is exempt from the requirements of Chapter 1200-2-5 with respect to radioactive materials covered by this general license, except that such person using the Mock Iodine-125 described in part (a)8 shall comply with the provisions of 1200-2-5-.17, 1200-2-5-.23, and 1200-2-5-.24.

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#### NOTE

If larger quantities or forms of radioactive material other than those specified in the general license are required, an "Application for Radioactive Material License," Form RHS 8-5 should be filed. Copies may be obtained by writing to the address in 6 above.